NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANARDAN J. DESAI, PRAVINA DESAI and JAYANT DESAI,	:	**OPINION**
Plaintiffs,	:	Civ. No. 12-2995
v.	:	
SORIN CRM USA, INC. (f/k/a ELA MEDICAL INC.), et al.,	:	
Defendants.	:	

Walls, Senior District Judge

Defendant Biotronik moves to dismiss this matter and for judgment on the pleadings under Federal Rules of Civil Procedure 12(b)(6) and 12(c). Plaintiffs Janardan J. Desai, Pravina Desai, and Jayant Desai oppose the motion, and cross move for leave to file a second amended complaint under Federal Rule of Civil Procedure 15(a). Under Federal Rule of Civil Procedure 78, the Court grants the motion to dismiss and denies the motion to amend without oral argument.

FACTUAL AND PROCEDURAL BACKGROUND

This is an action brought the New Jersey Product Liability Act (the "PLA") involving an allegedly defective defibrillator lead distributed by Defendant Biotronik. Am. Compl., Second Count ¶ 5. Plaintiffs allege that Co-Defendant Sorin's Implantable Cardiac Defibrillator ("ICD") device (Model number OATIO VR 6250, Serial Number 644YC328) was surgically implanted in

NOT FOR PUBLICATION

Mr. Desai on or about April 9, 2008. *Id.*, Second Count ¶ 2. Plaintiffs contend that Biotronik's Lead (Serial No. 10287936), was an integral part of Sorin's ICD. *Id.*

Plaintiffs allege that Mr. Desai attended regular follow-up visits with his cardiologist. Opp. at 1. On or about July 4, 2012, Mr. Desai was home with his wife and son, Plaintiffs Pravina Desai and Jayant Desai, when he was allegedly "suddenly and violently overtaken by numerous painful convulsions." Am. Compl., First Count ¶ 3. He was transported by ambulance to the emergency room of Christ Hospital in Jersey City. *Id.*, First Count ¶ 4; Opp. at 1. Plaintiffs contend that diagnostic testing revealed that Mr. Desai had suffered in excess of twenty electrical shocks to the heart, causing ventricular tachycardia as a direct and proximate result of a defective "fractured" lead wire of the ICD. Am. Compl., First Count ¶ 4.

On April 4, 2012, Plaintiffs filed a Complaint in the Superior Court of New Jersey, Law Division, in Hudson County. On May 18, 2012, counsel for Co-Defendant Sorin filed a Notice of Removal to this Court. ECF No. 1. A Consent Order to permit Plaintiffs to amend their Complaint to add Biotronik as a defendant, and to extend Sorin's time to answer was granted by this Court on May 23, 2012.

On June 1, 2012, Plaintiffs filed an Amended Complaint which named Biotronik as a defendant. ECF No. 4. On July 5, 2012, Plaintiffs and Defendant Sorin executed a Stipulation of Dismissal Without Prejudice based on Defendant's representations that they did not manufacture, design, or sell the sensory lead wire at issue. ECF No. 5. On September 10, 2012, Defendant Biotronik filed an Answer and Affirmative Defenses to Plaintiffs' claims. ECF No. 11. On September 30, 2012, Biotronik filed a motion to dismiss Plaintiffs' Amended Complaint. ECF No. 13. Plaintiffs filed their opposition on October 22, 2012. ECF No. 16.

NOT FOR PUBLICATION

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(c) provides, in pertinent part, that "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." The pleadings are considered closed after the complaint and answer are filed, along with any reply to additional claims. *Arnold v. New Jersey*, 03-cv-3997, 2007 WL 1381757, at *2 (D.N.J. May 9, 2007) (citations omitted).

"Under Rule 12(c), judgment will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Bayer Chemicals Corp. v. Albermarle Corp.*, 171 Fed. Appx. 392, 397 (3d Cir. Mar. 21, 2006) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988) (citations and quotations omitted)).

"The standard applied to a Fed.R.Civ.P. 12(c) motion for judgment on the pleadings is similar to that applied to a Fed.R.Civ.P. 12(b)(6) motion to dismiss." *Haynes v. Metropolitan Life Ins. Co.*, 94 Fed. Appx. 956, 958 (3d Cir. Apr. 20, 2004) (citation omitted). "In reviewing the grant of a Rule 12(c) motion, [the court] must view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Bayer*, 171 Fed. Appx. at 397 (internal quotation marks and citation omitted). The court "need not accept as true legal conclusions or unwarranted factual inferences." *Bayer*, 171 Fed. Appx. at 397 (internal quotation marks and citation omitted). As with a Rule 12(b)(6) motion, in deciding a Rule 12(c) motion, the court typically does not consider matters outside the pleadings. *Mele v. Federal Reserve Bank of New York*, 359 F.3d 251, 257 (3d Cir. 2004). The court may consider matters of public record, orders, and exhibits attached to the complaint. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994).

NOT FOR PUBLICATION

Similarly, in deciding a motion to dismiss for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007). Under Federal Rule of Civil Procedure 8(a)(2), the complaint need only include "a short and plain statement of the claim showing that the pleader is entitled to relief." At the same time, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). As a result, the complaint must contain more than "bare-bones allegations" or "threadbare recitals of the elements of a cause of action." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678). The plaintiff must allege "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008).

In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court may consider only the allegations of the complaint, documents attached or specifically referenced in the complaint if the claims are based upon those documents and matters of public record. *Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007); *Sentinel Trust Co. v. Universal Bonding Ins. Co.*, 316 F.3d 213, 216 (3d Cir. 2003).

Federal Rule of Civil Procedure 15(a)(2) allows a party to amend its pleading by leave of court when justice so requires. Leave to amend pleadings is to be freely given. *Foman v. Davis*,

371 U.S. 178, 182 (1962). The decision to grant leave to amend rests within the discretion of the court. *Id*. Leave to amend may be denied on the basis of: (1) undue delay; (2) bad faith or dilatory motive; (3) undue prejudice to the opposing party; and (4) futility of amendment. *Id.* "Only when these factors suggest that amendment would be 'unjust' should the court deny leave." *Arthur v. Maersk, Inc.*, 434 F.3d 196, 203 (3d Cir. 2006) (internal citations omitted).

DISCUSSION

1. Preemption under the Medical Device Amendments

a. Premarket Approval

The Medical Devices Amendments ("MDA"), 21 U.S.C. § 360c *et. seq.* to the FDA, 21 U.S.C. § 301 *et. seq.*, authorize the FDA to regulate the safety and effectiveness of medical devices. Under the MDA, medical devices are divided into three categories according to the risks that the devices present. Class III devices, which includes the device in this case, are those that are either too unproven to be rendered safe by general controls or that present a potential for unreasonable risk of illness or injury. 21 U.S.C. § 360(a)(1)(C). The MDA usually requires Class III devices to receive premarket approval before the FDA will allow them to be sold. The FDA will approve the devices for distribution only if it is satisfied that the device is reasonably safe and effective for its intended purpose. 21 U.S.C. § 360(e)(d)(2).

Defendant Biotronik argues that the Medical Device Amendments to the Federal Food, Drug & Cosmetics Act ("FDA") expressly preempt the type of claim being asserted by Plaintiffs. Mot. at 1, 3-8; 21 U.S.C. § 360c *et. seq.* Plaintiffs respond that Defendant's allegation that the devices implanted in Plaintiff were Class III medical devices subject to premarket approval was insufficiently supported. Opp. at 4-6. In the alternative, Plaintiffs allege that should the Court

find that the lead wire and ICD device were subject to pre-market approval, all of Plaintiffs' claims would still not be preempted. *Id.* at 4-13.

This Court rejects Plaintiffs' contention that Defendant's "generic reference" to the FDA public database of premarket approvals is insufficient to establish which forms of the ICD device and lead wire received premarket approval. In *Desabio v. Howmedica Osteonics Corp.*, as example, the defendant cited to a web address for the FDA's premarket approval of the devices at issue in support of its motion to dismiss. 817 F. Supp. 2d 197, 201 (W.D.N.Y. 2011). The web address given to the court did not lead to any relevant information, but the court conducted its own independent search of the FDA's website, and confirmed that the devices did receive premarket approval. *Id.* The court took judicial notice of that fact based on its independent search. *Id.*; *see also Stengel v. Medtronic Inc.*, 676 F.3d 1159, 1167 (9th Cir. 2010) ("Because the accuracy of FDA records cannot reasonably be questioned, the premarket approval status of [the device] is a fact subject to judicial notice."); *Cornwell v. Stryker Corp.*, No. 1:10-cv-00066-EJL, 2010 WL 4641112, at *3 (D. Idaho Nov. 1, 2010) (confirmed premarket approval via independent search of FDA website); *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("The Court may take judicial notice of and consider the public record of the FDA . . . ."); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 530-31 (S.D. Tex. 2009); *Ali v. Allergan USA, Inc.*, No. 1:12-cv-115, 2012 WL 3692396, at *1 (E.D. Va. Aug. 23, 2012).

Plaintiffs' reliance on *Kavalir v. Medtronic, Inc.* is misplaced. Case No. 07-cv-0835, 2008 WL 4087950 (N.D. Ill. Aug. 27, 2008). In *Kavalir*, the plaintiff had four different ICDs with various lead wires implanted over a six year period. *Id.* at *1-*2. The court was worried that "none of the documents attached . . . refer to the . . . lead wires used to implant the ICDs in Plaintiff, the part Plaintiff contends caused her injuries." *Id.* at *4. The court also expressed the

concern that the provided documents "did not make clear what specific form or forms" of the ICD leads had received premarket approval. *Id.* In contrast, Biotronik's lead wire is the only one at issue, and is specifically identified by the FDA's public records as having received its own premarket approval on January 27, 2006 under PMA Number P980023. This Court takes judicial notice of the FDA's website, and holds that it establishes premarket approval of the Biotronik lead.[1]

b. Preemption

The Medical Devices Amendments contain an express preemption provision with two elements that must be satisfied for preemption to occur:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360(k)(a).

In *Riegel v. Medtronic*, the Supreme Court held that state laws are preempted by the MDA if: (1) the Federal Government has established "specific requirements applicable to a particular device," and (2) the plaintiff's claims are based on "state requirements" related to safety and effectiveness that are "different from, or in addition to" the federal requirements. 552 U.S. 312, 315 (2008) (citing 21 U.S.C. § 360c). The Supreme Court reasoned that a state law demanding a manufacturer's devices "to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." *Id.* at 325. Included in the meaning of "state

[1] Defendant Biotronik has also submitted a hard copy of the FDA's letter granting premarket approval with its Reply papers. *See* Reply, Ex. C.

NOT FOR PUBLICATION

requirements" are common law causes of action, such as negligence, strict liability, and breach of implied warranty. *Id.* at 324-25, 327-28.

Federal courts in various circuits have also held that, to avoid § 360k(a) preemption, a plaintiff must allege a violation with sufficient facts to render the alleged violation plausible under *Twombly* and *Iqbal*. *See, e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *14 (M.D.N.C. Aug. 5, 2009); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008); *Gross v. Stryker*, 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012). Conclusory allegations that the defendant violated FDA regulations in the manufacturing, labeling, or marketing of the premarket approved medical device are not sufficient to state a parallel state-law claim and avoid preemption. *Parker*, 584 F. Supp. 2d at 1301. *See also Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) ("Plaintiffs cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption.").

As in *Riegel*, Defendant Biotronik argues that Plaintiffs' statutory Product Liability Act claims are preempted. Mot. at 10. Plaintiffs contend that its claims are parallel state claims under the New Jersey Product Liability Act, and they intend to assert, and if necessary, to amend their Complaint to explicitly include a claim under the New Jersey PLA for Defendant's alleged deviation from the federal requirements for Class III lead wires. Opp. at 7.

As said, the Federal Government has established specific requirements applicable to Biotronik's lead wire. Plaintiffs' claims of, *inter alia*, negligence, defective design, and failure to warn stem from state common law. Plaintiffs would only be able to prevail on the New Jersey PLA claims if they proved that the lead wire, as designed, manufactured, and distributed, was

defective and unreasonably dangerous. It follows that liability would necessitate a finding that the lead wire – designed, manufactured, and labeled in a way that the FDA deemed safe and effective – was both defective and unreasonably dangerous. Such a determination would necessarily constitute "a requirement 'different from, or in addition to,'" the standard required by federal authorities. *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001) (citation omitted); *see also Horn v. Thoratec Corp.*, 376 F.3d 163, 176 (3d Cir. 2004). This is the exact situation when the MDA requires preemption.

These claims in the amended complaint are consequently expressly preempted. "Generalized common law theories of liability . . . are precisely the types of claims the MDA sought to preempt." *Williams v. Cyberonics, Inc.*, 388 Fed. Appx. 169, 171 (3d Cir. July 30, 2010) (citing *Riegel*, 552 U.S. at 325; *Horn*, 376 F.3d at 173). Many courts, both within and outside this district, have evaluated nearly identical claims, and deemed them expressly preempted. *See, e.g.*, *Horn*, 376 F.3d 163 (dismissing all state common law tort claims); *Banner v. Cyberonics, Inc.*, No. 08-0741, 2010 WL 455286 (D.N.J. Feb. 4, 2010) (dismissing claims for defective manufacturing, defective design, and breach of implied warranties); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522 (S.D. Tex. 2009) (dismissing claims for, *inter alia*, strict liability and negligence), *aff'd*, 631 F.3d 777 (5th Cir. 2011); *Covert*, 2009 WL 2424559 (dismissing claims for failure to warn, defective manufacturing, defective design, negligence and recklessness, and breach of implied warranties); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (dismissing claims for strict liability, negligence and recklessness, and breach of express and implied warranties); *Parker*, 584 F. Supp. 2d 1298 (dismissing claims for failure to warn, manufacturing defect, design defect, breach of express and implied warranties, breach of implied

NOT FOR PUBLICATION

warranty of fitness, breach of implied warranty of merchantability, and negligence and recklessness).

With regard to Plaintiffs' proposed second amendment of the Complaint to explicitly include claims of an alleged deviation from the federal requirements for Class III lead wires, the amended claims remain fatally conclusory:

> 7. Based on information and belief the lead wire manufactured by Biotronik deviated from the ICD/lead wire's federally approved design and manufacturing process and/or federal requirementS *[sic]* including but not limited to 21 C.F.R. 820, 814(b), and 814.39 pertaining to manufacturing processes.
>
> 8. Based upon information and belief it is the deviations from the federally approved design and manufacturing processes that caused the lead wire to fracture causing the lead wire and/or ICD device to malfunction on or about April 9, 2008, which was the direct and proximate cause of my *[sic]* injuries sustained therefrom. *[sic]* on April 9, 2008.
>
> 9. Deviations from the federally approved design and manufacturing process for the lead wire and ICD device rendered the device/lead wire unreasonably fit, unsuitable and unsafe for its intended purpose, under the law of New Jersey.

Pl.s' Cross Motion, Ex. 4 (Pl.s' Proposed Second Am. Compl.), Second Count ¶¶ 7-9. These allegations fail to assert the facts necessary, or indeed, any facts at all, to establish a claim that would parallel a violation of federal law, or even meet the federal pleading standard. Plaintiffs' claims, both in the amended complaint and proposed second amended complaint, are devoid of any explanation as to how Biotronik allegedly violated federal regulations in its design or manufacture of the lead wire, or even what about the device is "defective" or "unreasonably dangerous." *Callaway v. Am. Med. Sys., Inc.*, No. 11-00193, 2011 WL 7724268, at *4 (W.D. La. 2011). Both complaints allege no specific wrongdoing on the part of Biotronik, other than to conclusory state that it is liable for all of Plaintiffs' damages. "[M]erely because a device does not work as intended is not proof that the device was not appropriately manufactured." *Banner*, 2010 WL 455286, at *4. *See also Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D.

Minn. 2008) ("Plaintiff is ultimately wrong when he assumes that premarket approval guarantees the device is completely safe.").

Plaintiffs also consistently fail to allege any "cognizable link" between Biotronik's alleged federal violations and Mr. Desai's injury. *Horowitz*, 613 F. Supp. 2d at 280; *Covert*, 2009 WL 2424559, at *15 (granting *Twombly* motion after concluding that the complaint failed to allege "any particular non-conclusory link between [the] alleged wrongdoing and [plaintiff's] particular injuries, let alone a causal one"). *See also Parker*, 584 F. Supp. 2d at 1301-02 (noting that plaintiff's complaint was deficient in that it failed to provide any factual detail substantiating her claim that the device was defective as a direct result of defendants having manufactured it in violation of the premarket approval process). *Gross v. Stryker Corp.*, among other cases, held that broad references to federal regulations in pleadings are insufficient:

> Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel*, as well as the pleading requirements articulated in *Twombly*, *Iqbal*, and *Fowler*. This Court requires a greater level of specificity in pleading a parallel claim, rather than allowing claims premised on violations of general regulations to go forward merely because plaintiffs will supplement their pleadings at trial.

858 F. Supp. 2d 466, 495-96 (W.D. Pa. 2012) (internal citations omitted). Plaintiffs themselves even admit in their opposition that they cannot, at this point in time, specify how Biotronik's lead wire deviated from FDA approved design and manufacturing processes. Opp. at 13-16 ("Plaintiffs do not currently have access to the specific federal requirements for the leads manufactured by Biotronik. Plaintiffs will promptly seek to obtain this information from Defendants through discovery.").

Plaintiffs contend that they should be permitted to allege unspecified deviations from FDA manufacturing requirements at this stage, and "fill in the blanks" later as to how Biotronik deviated from those requirements. But a plaintiff must successfully plead a claim before

obtaining discovery, and not the other way around. Such a premature request for discovery is inapposite to Rules 8 and 11(b) of the Federal Rules of Civil Procedure. *See Kinetic Co. v. Medtronic, Inc.*, No. 08-CV-6062, 2011 U.S. Dist. LEXIS 42398, at *13 (D. Minn. Apr. 19, 2011) (stating that "[a] plaintiff is permitted to take discovery to find evidence to support a properly pleaded claim for relief; a plaintiff is not permitted to take discovery to fish for claims of which it is not aware."); *Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 585 (C.D. Cal. 2010) ("A plaintiff who fails to meet the pleading requirements of Rule 8 is not entitled to conduct discovery with the hope that it might permit her to state a claim."); *Horowitz*, 613 F. Supp. 2d at 280 ("[M]ere promises of future allegations are not sufficient [to state a cause of action]."); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010) ("The district court did not abuse its discretion in denying Plaintiffs' motion to reconsider the dismissal order and grant their belated request for discovery to see if they could find such a requirement.").

Judge Hayden of this District recently addressed this very issue. In *Hayes v. Howmedica Osteonics Corp.*, plaintiff argued that the pleading requirements of Federal Rules of Civil Procedure 8 and 11 should be relaxed for claims involving a premarket approved device. No. 08-6104, 2009 WL 6841859 (D.N.J. Dec. 15, 2009). In a bench opinion, Judge Hayden held that "*Twombly*, and in this Circuit, *Phillips* and *Fowler*, do not distinguish between and among different types of cases. It would be wrong for this Court to rule that this plaintiff because of her particular injury and theory of harm has a right to support [her claim] through discovery as opposed [to] allegations in the complaint . . . ." *Id.* at 7.

Furthermore, the cases cited by Plaintiffs in support are inapposite. In *Cornett v. Johnson & Johnson*, while plaintiffs were permitted to proceed with a manufacturing defect claim based

on alleged deviations, the factual underpinnings of their defect claim were pled with specificity. 414 N.J. Super. 365 (App. Div. 2010), *aff'd as modified*, 211 N.J. 362 (2012). The *Cornett* plaintiffs, as example, pointed to an FDA warning letter highlighting the device's polymer coating. 414 N.J. Super. at 398. In *Walker v. Medtronic, Inc.*, the plaintiff similarly stated that she wished to pursue a theory of recovery based on a violation of the terms of the device's premarket approval. The court noted that "[plaintiff] details several discovery matters yet to be resolved." No. 2:07-00317, 2008 WL 4186854, at *3 (S.D.W.Va. Sept. 9, 2008). The court concluded that the complaint did not "adequately allege the type of claim which might survive *Riegel*." *Id.* In *Braden v. Tornier, Inc.*, Plaintiffs fail to note that the court did not allow the case to go forward on the basis of its current, inadequately pled complaint, but granted leave to amend, highlighting that plaintiffs had not previously amended their complaint. No. C09-5529RJB, 2009 WL 3188075, at *5 (W.D. Wash., Sept. 30, 2009). Although courts have acknowledged that plaintiffs might have limited access to crucial information, this Court's research suggests that no courts have let cases enter discovery based on the type of generalized allegations that are present here. *Cf. Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 598 (8th Cir. 2009).

c. Derivative Claims

Plaintiffs Pravina Desai and Jayant Desai assert claims against Defendant Biotronik for emotional distress. Am. Compl., Third Count ¶ 3. These derivative claims are preempted since the underlying claims cannot stand. *Kemp v. Medtronic*, 231 F.3d 216, 237 (6th Cir. 2000) ("In light of the foregoing analysis finding that Elizabeth Kemp's claims are preempted by § 360(k) of the MDA, Clifford Kemp's derivative spousal claim is similarly preempted."); *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 52 (D. Mass 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995) (holding that a

claim for negligent infliction of emotion distress was preempted); *see also Reigel*, 522 U.S. at 321 (affirming dismissal of loss of consortium claim because "it was derivative of the pre-empted claims"); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1288, 1290-91 (M.D. Fla. 2009), *aff'd*, 624 F.3d 1296 (11th Cir. 2011).

2. Second Amendment of the Complaint

An amendment is considered futile if it advances a claim or defense that is legally insufficient on its face. Courts may properly deny a motion to amend when the amendment would not withstand a motion to dismiss. *Massarsky v. Gen. Motors Corp.*, 706 F.2d 111, 125 (3d Cir. 1983).

With respect to futility, "[it is] clear that an amendment would be futile when 'the complaint, as amended, would fail to state a claim upon which relief could be granted.'" *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1332 (3d Cir. 2002) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)); *see also Harrison Beverage Co. v. Dribeck Imps., Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) (reasoning that an amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face" (citations and footnotes omitted)). As such, "[i]n assessing futility, the district court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *Burlington*, 114 F.3d at 1434 (citing *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996) (further citation omitted)). The Court therefore must accept all factual allegations as true "as well as the reasonable inferences that can be drawn from them." *Brown v. Philip Morris, Inc.*, 250 F.3d 789, 796 (3d Cir. 2001).

Here, in light of Plaintiffs' admission that they cannot meet the necessary pleading hurdle without discovery, any amendment would be futile, and the motion to amend is denied.

NOT FOR PUBLICATION

CONCLUSION

The Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted and Defendant Biotronik is entitled to the dismissal of the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiffs' motion to amend is also denied on grounds of futility.

January 15, 2013

/s/ William H. Walls
United States Senior District Judge